

Notice of Allowability

Application No.

09/383,054

Applicant(s)

EDWARDS ET AL.

Examiner

Art Unit

Frank I. Choi

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Second Supplemental Brief on Appeal (9/17/2004).
2. ☒ The allowed claim(s) is/are 50[renumbered as claim 1], 52-69[renumbered as claims 2-19], 91[renumbered as claim 20], 93-108[renumbered as claims 21-36], 128-130[renumbered as claim 37-40].
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |



REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance: In consideration of the Second Supplemental Brief on Appeal (9/17/2004), the claimed invention is neither expressly disclosed nor fairly suggested by the prior art in that the prior art does not disclose or make obvious particles consisting of stabilized protein, phospholipids, at least 10 weight percent, and, optionally buffer salt, which are prepared by spray drying a mixture of protein, phospholipids, optionally buffer salt, and organic solvent or organic and aqueous solvents.

With respect to the first of the 35 USC 112, 2nd paragraph rejections, Applicant has made clear that the "consists of" transitional phrase is intended to modify the "comprising" transitional phrase in paragraph (b) of the claims (Brief (9/17/2004), pgs. 3,4). With respect to the second of the 35 USC 112, 2nd paragraph rejections, Examiner notes that the MPEP clearly indicates that a 2nd paragraph rejection may be based on Applicant's admissions. As such, if Applicant makes statements or arguments which indicate that the invention is other than claimed, then a rejection under the 2nd paragraph of section 112 is proper. See MPEP Sections 2171, 2172(II). For example, arguing "consisting essentially of" when the claims recite "consist" (See page 8 of the Supplemental Brief (12/12/2004)). Applicant, however, has clarified that the reference to phosphate salt was as merely as an example and not a statement of the scope of the invention and that Applicant's claimed invention is as set forth in the pending claims, i.e. including the narrower scope of "consist" and not the broader scope of "consisting essentially of" (Brief (9/17/2004), pgs. 5,6). As such, the 35 USC 112, 2nd paragraph rejections are withdrawn.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

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fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FIC

May 10, 2005



**S. MARK CLARDY
PATENT EXAMINER
GROUP 1200**

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